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**STATEMENT OF
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BEFORE THE
SUBCOMMITTEE ON REGULATORY REFORM AND OVERSIGHT
OF THE
COMMITTEE ON SMALL BUSINESS
U.S. HOUSE OF REPRESENTATIVES**

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INTRODUCTION

Good morning, Mr. Chairman and Members of the Subcommittee. I appreciate this opportunity to discuss with you the Environmental Protection Agency's (EPA) recent rule to expand reporting on lead and lead compounds under EPA's Toxics Release Inventory (TRI) Program.

As you may recall, the new TRI lead rule was one of several regulations carefully reviewed by the Administration upon entering office. After a thorough review, the new lead regulation was endorsed by the President and Governor Whitman and became effective in April 2001. The new rule requires any facility, otherwise subject to Section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) reporting, that manufactures, processes, or otherwise uses 100 pounds or more of lead or lead compounds, to report annually to EPA its releases of lead. This rule significantly expands the information available to the public about the presence and releases of lead in our communities.

We believe that it is particularly important to provide the public with more information on lead releases given the well-documented hazards of lead, particularly to our Nation's children. Toxic effects from lead exposure can result years after releases and exposures occur because of lead's ability to remain in the environment, build up in the environment and bioaccumulate, particularly in humans. We firmly believe that public access to such information contributes positively to the public's ability to understand environmental issues and to its ability to make better "protection" decisions in daily life.

Before I discuss the rule, I would like to first provide a little background on the TRI program and the factors that led to the development of the rule. As you know, through Section 313 of EPCRA and the Pollution Prevention Act of 1990 (PPA), Congress mandated that information on toxic chemical releases and other waste management activities be collected in a publicly available database. Since its implementation in 1987, the TRI has been the centerpiece of the Agency's right-to-know programs and has proven to be a very powerful tool for assisting communities in protecting their own environment and for making businesses more aware of their chemical releases. Given the success of the program and its important contribution to the decrease in environmental releases of toxic chemicals, EPA has continued to expand the program to fill important data gaps in the public's right-to-know while working to reduce the reporting burden on affected businesses.

TRI BACKGROUND

Under the authority of EPCRA and PPA, the TRI program requires certain facilities with 10 or more employees in specific industry sectors to report to EPA and to the States their releases and other waste management activities for over 650 chemicals. Chemicals on the TRI list must meet specific,

Congressionally-mandated toxicity criteria. Generally, if a covered facility currently manufactures or processes more than 25,000 pounds of a listed chemical, or otherwise uses more than 10,000 pounds, it is required to report its annual chemical releases under TRI. The purpose of the program is to provide information to the public on releases and other waste management of toxic chemicals its communities. EPA accomplishes this by gathering data and making it accessible to the public through the Internet and other media. TRI data has proven to be a very valuable and useful source of information not only to communities but to businesses as well. Communities use TRI data to: learn about their local environment and potential exposures to toxic chemicals; begin dialogues with local facilities to encourage the reduction of emissions; develop pollution prevention plans thereby improving safety; and improve local environmental conditions. Businesses use TRI data to: identify opportunities for pollution prevention; increase efficiency in processes; demonstrate environmental progress; and improve local environmental conditions. These uses of the data are integral to the success of the TRI program in encouraging decreases in the release of toxic chemicals to the environment.

PERSISTENT AND BIOACCUMULATIVE TOXIC CHEMICALS

The basis of the TRI lead rule is EPA's determination that lead and lead compounds are persistent, bioaccumulative, and toxic chemicals, or PBT chemicals. PBT chemicals comprise a category of toxic chemicals that may pose an increased potential to cause harm to human health and the environment compared to chemicals that do not exhibit these properties. PBT chemicals are of particular concern because they remain in the environment for long periods of time (i.e., persistence), build up in the environment, accumulate in plants, animals, and humans (i.e., bioaccumulation), can be

transferred within the food chain, and may cause a range of serious toxic effects such as neurological disorders, reproductive and developmental problems, genetic damage, cancer, and environmental toxicity (i.e., toxicity). All else being equal, PBT chemicals present a greater likelihood for exposure when compared to toxic chemicals that do not persist or bioaccumulate. As such, PBT chemicals have a greater potential to cause serious human health and environmental effects at relatively lower levels of release and exposure.

Over the years, PBT chemicals have been the focus of a great deal of public attention and concern due to the public health and environmental problems they have caused. EPA shares the public's concern regarding PBT chemicals and has made these chemicals a focus for Agency initiatives and actions. In 1998, faced with concerns that the current TRI reporting thresholds left significant data gaps for PBT chemicals, EPA began working on a proposal to add certain PBT chemicals to the list of TRI chemicals and to lower reporting thresholds for certain PBT chemicals. In October 1999, EPA published a final rule to lower the activity threshold quantity for reporting on PBT chemicals to 100 pounds and to 10 pounds for a subset of PBT chemicals that are highly persistent and highly bioaccumulative. This rulemaking, in conjunction with the subsequent 2001 TRI lead rulemaking, established the criteria EPA uses for identifying PBT chemicals for the TRI program. The criteria include:

- < persistence of the toxic chemical in water, soil, or sediments; and
- < bioaccumulation of the toxic chemical in plants, animals, and humans; and
- < listing on the EPCRA Section 313 list of toxic chemicals.

The PBT rule is currently in effect, and last year, facilities reported their releases and other waste management data for PBT chemicals for the year 2000 – the first reporting year under the lower thresholds established by this rule. These data, which have recently been made available to the public, have contributed significantly to the public's knowledge about chemicals being used and released in their communities.

THE TRI-LEAD RULE: LEAD AS A PBT CHEMICAL

After EPA published the proposed PBT rule in January 1999, the Agency received numerous comments requesting that lead and lead compounds be included as a PBT chemical under EPCRA Section 313 and that lower reporting activity thresholds be set. To address these comments, EPA applied its PBT criteria to lead and lead compounds to assess its persistence and bioaccumulation.

PERSISTENCE OF LEAD

EPA evaluated the persistence of lead in the environment and concluded that lead meets the PBT criterion for classification as highly persistent because lead is a metal and metals cannot be destroyed – they persist indefinitely. Lead is highly persistent and because it is a PBT chemical, there is a greater potential for exposure to lead.

BIOACCUMULATION OF LEAD

In assessing the bioaccumulation of lead, EPA considered bioaccumulation data both in aquatic plants and animals and humans. EPA determined that the data on oysters, snails, algae, phytoplankton, and blue mussels, as well as the human data, clearly support a conclusion that lead and lead compounds are bioaccumulative. There are extensive peer-reviewed human data demonstrating that repeated

exposure to low levels of lead results in a build-up (accumulation) of lead in the bones of the human body where it can remain for many years. Numerous studies have shown that lead that has accumulated in bone can later move from the bone to blood, especially during periods of increased bone mineral loss (such as occurs, for example, during pregnancy, breast feeding, menopause, old age). It can then reach organs and other tissues and cause toxicity to adults, fetuses, and infants.

TOXICITY OF LEAD

The toxicity of lead to humans is well documented and undisputed. In adults, exposure to lead can cause neurological toxicity, damage to the kidneys, and hypertension. Of particular concern is the effect lead has on fetuses, infants, and children because they tend to be more susceptible to exposures of lead and are more sensitive to the toxicity it causes. Their exposure to lead can lead to permanent brain damage. Even at very low dose levels, it can result in diminished IQ levels, impaired neurobehavioral development, decreased stature and growth, and impaired hearing.

SCIENCE ADVISORY BOARD (SAB) REVIEW

From its analysis of lead, EPA concluded that lead and lead compounds met the criteria for designation as persistent, bioaccumulative, and toxic chemicals. More specifically, EPA preliminarily concluded in its August 1999 proposal that lead and its compounds met the criteria for being classified as highly persistent, highly bioaccumulative toxic chemicals. EPA believes that the bioaccumulation data clearly show that lead and lead compounds significantly bioaccumulate in humans. EPA further believes that lead bioaccumulates in certain aquatic plants and animals. However, during the public comment period, questions were raised challenging the sufficiency of the aquatic data to support the conclusion

that lead and lead compounds are highly bioaccumulative. In addition, while there are extensive, high quality data in humans that clearly indicate that lead and lead compounds bioaccumulate in humans, EPA recognized that it did not clearly indicate in the proposed TRI rule how the data would be used to distinguish between bioaccumulative and highly bioaccumulative categories. Consequently, EPA determined that the data clearly supported a finding that lead and lead compounds are bioaccumulative and deferred on its determination as to whether lead and lead compounds are highly bioaccumulative. EPA finalized the rule in January 2001 and, based on the conclusion that lead and lead compounds are, at least, bioaccumulative, set the reporting thresholds at 100 pounds.

Before determining whether lead and lead compounds are highly bioaccumulative, EPA believes that it would be appropriate to seek external scientific peer review from its Science Advisory Board, and EPA intends to do so. The external peer review would address the question of whether lead and lead compounds should be classified as highly bioaccumulative. The external peer review would address the issue of how lead and other, as yet unclassified metals, such as cadmium, should be evaluated using the PBT chemical framework, including which types of data (and which species) are most suitable for these determinations.

SCHEDULE FOR SCIENCE ADVISORY BOARD REVIEW

Shortly after the lead rule was finalized, the Agency began to plan efforts to seek advice from its Science Advisory Board as discussed in the lead rule. To this end, the Agency convened a team of scientists under the auspices of the Agency's Risk Assessment Forum to develop a "White Paper" that would serve as a summary of the bioaccumulation data available for lead and that would contain

specific charge questions for the SAB to address.

EPA originally planned to have the SAB review take place last summer or fall. However, during the drafting of the SAB White Paper, discussions that EPA had with external stakeholders, as well as concerns expressed formally from Congress, led EPA to recognize the need to develop Agency- wide guidance for assessing the hazards and risks of metals and metal compounds. Last December, EPA's Deputy Administrator informed stakeholders of our intentions and charged the Agency's Science Policy Council (SPC) with the responsibility to prepare an Action Plan for identifying the primary elements that should be addressed in developing a cross-Agency metals assessment framework. The Action Plan is intended to propose a process that will culminate in the production of the framework and related guidance for characterizing and ranking the hazards and risks posed by metals. The development of the Action Plan has involved input from stakeholders and will include discussion of the issues that need to be addressed in the framework and how we intend to move forward.

Once developed, the Action Plan will be the subject of an SAB advisory. The SAB advisory will provide an opportunity for early input by the SAB on this proposed approach to developing broader-based guidance on the assessment of metals and metal compounds. Upon conclusion of the SAB's advisory, the Agency will develop a framework for the evaluation of metals and metal compounds and guidance on the characterization and ranking of metals. The Agency will submit the framework and guidance for peer review by the SAB. At that same time, EPA also plans to submit to the SAB for review the specific issue of whether the application of the bioaccumulation data used in the

TRI lead rulemaking would result in a classification of lead and lead compounds as highly bioaccumulative.

This week, EPA is announcing, through a Federal Register notice, the availability for public comment of the *Draft Action Plan for the Development of a Framework for Metals Assessment and Guidance for Characterizing and Ranking Metals*, (EPA/630/P-02/003A), which was prepared by a cross-Agency workgroup under the auspices of the Science Policy Council. The draft Action Plan proposes that the development of both documents involve stakeholder workshops and SAB peer review and proposes dates for these workshops and SAB reviews. The date proposed for the SAB peer review of the draft metals framework is June 2003. The date proposed for the peer review of the draft metals guidance and the highly bioaccumulative issues pertaining to the lead rule is November 2003. The draft Action Plan proposes December 2003 as the date for completion of the metals framework document and May of 2004 as the date for completion of the metals guidance document.

COMPLIANCE AND ENFORCEMENT

EPA takes a problem-solving approach to addressing compliance issues and devising the best strategies for non-compliance. EPA uses many tools in achieving that mission. EPA's integrated approaches strategically use available tools – incentive programs, compliance assistance, investigations, settlements – in a manner targeted and tailored to particular problems and situations to produce the most benefit to the public and the environment.

To encourage self-monitoring and to reduce the need for direct enforcement, EPA's

enforcement office created the “Policy on Compliance Incentives for Small Businesses” (also known as the Small Business Policy) and a policy called “Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations” (also known as the Audit Policy). These policies, the first directed specifically to account for small businesses concerns and the second directed toward all other businesses, provide for up to 100 percent reduction in otherwise applicable gravity-based penalties for those violations that are voluntarily disclosed to the Agency in accordance with the terms of each policy. Thousands of businesses have self disclosed and successfully resolved violations under these policies without any penalty and long before it became necessary for the Agency to initiate any investigation.

Now I would like to discuss EPA’s compliance assistance and outreach efforts for complying with the TRI lead rule. This Administration believes the preferred approach to achieving compliance with new rules is by emphasizing compliance assistance during the first year rather than direct enforcement. Indeed, for the lead rule, the President specifically directed EPA to provide compliance assistance to affected businesses, especially small businesses, to help them prepare their first release reports due by July 1 of this year under this new rule. EPA’s direct enforcement priorities for existing TRI requirements focus on where we may see areas of noncompliance and the potential for significant environmental or public health harm.

For the first new TRI lead reports, EPA has worked hard in providing compliance assistance and outreach, especially for small businesses, for the first year reporting deadline. Within the past year, the Agency issued a technical guidance document to assist facilities in complying with the new lead rule.

This document was developed through a public notice and comment process that included a meeting with interested stakeholders so that they could provide feedback directly to EPA. Also in this first year, EPA sponsored workshops specifically on the new lead rule. These workshops were held in the Fall of 2001 in the northeast, mid-Atlantic, southeast, southern, central, and western geographic areas of the country. These workshops were developed specifically for the first time reporter. They provided an overview of the TRI program and the reporting requirements, an overview of PBT chemicals and the reporting requirements that apply to these chemicals, a detailed overview of the new reporting requirements for lead and lead compounds, including the use of emission factors for estimating quantities for activity thresholds and releases, and finally other sources to refer to for further information.

Both the workshops and the availability of the draft and final versions of the guidance document were extensively publicized, through announcements published in the Federal Register, the Agency's TRI web page, and e-mail announcements sent out by EPA's Small Business Ombudsman, to trade organizations and interested parties, including the Small Business Administration, as well as through other EPA efforts. EPA also provides TRI assistance through its Compliance Assistance Centers (<http://www.assistancecenters.net/>), which cover all applicable Federal, State, and local environmental requirements for specific sectors. These centers provide specific information on each environmental requirement or direct links to the agency or industry site which addresses the compliance issue of interest. In addition, EPA's Office of Enforcement and Compliance Assistance's (OECA) National Compliance Assistance Clearinghouse (<http://cfpub.epa.gov/clearinghouse/>) provides similar

information for industries which do not have a dedicated center.

In addition to these specific efforts to address compliance with the lead rule, the Agency continues to work hard to provide compliance assistance for facilities generally. For example, EPA held more than forty workshops on compliance with the TRI reporting requirements, which also include the lead rule requirements, this spring throughout the country. More than 3000 people attended the workshops this spring. These annual spring workshops are especially helpful to those who will be responsible for reporting their releases and other waste management activities of lead and lead compounds for the first time. Also, the training materials used at these workshops are available on the Internet through the TRI web page. EPA has many more TRI compliance assistance resources and tools available through the Internet and telephone hotlines to assist small businesses with the reporting requirements.

I believe that our outreach to the small business community and our compliance assistance efforts to help small businesses comply with the new lead reporting requirements have been extensive. The Agency will continue to be diligent in our contacts with affected businesses to give them the assistance necessary to comply with the new regulation. Because the TRI program, which is in my office, has primary responsibility for compliance assistance efforts under TRI, OECA has a limited role to play in implementing the new TRI lead rule until after July 1, 2002, when the first reports are due. As with any new rule, EPA emphasizes compliance assistance during the first year of implementation rather than enforcement. For the new TRI lead reporting obligations, the Agency will devote most of its

resources to outreach and education about the lead rule, ensuring that companies have the necessary information and assistance to

comply. EPA will continue to promote our incentive policies and compliance information, but it is incumbent upon the regulated facilities to take advantage of these offerings.

In conclusion, I would like to reiterate EPA's strong commitment to providing public access to environmental information and our firm belief that public access contributes positively to our citizens' ability to understand environmental issues and to make better decisions in their daily lives. An informed public can hold government and industry accountable for pollution control efforts.

Thank you, Mr. Chairman and Members of the Subcommittee for the opportunity to appear today. I would be glad to answer any questions you may have at this time.